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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,173	03/01/2004	Fred H. Burbank	R0367-00103	1003

7590 09/11/2006

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,173	BURBANK ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 40-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 40-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/26/06, 7/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 8/23/06*.

DETAILED ACTION

1. This Office action is responsive to the amendments filed July 5, 2006. Claims 1 and 40-56 are pending. No claim has been added. Claim 1 has been amended. No claim has been cancelled.

Claim Objections

2. Claim 53 is objected to because of the following informalities:

At line 1, remove "and" between "claim 50" and "further".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 40-44, 46-47 and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US Patent No. 3,910,279).

In regards to claim 1, Okada et al. disclose a biopsy instrument capable of retrieving body tissue, having a longitudinal axis and comprising:

an elongated shaft 1 having a distal end 1a adapted for entry into a patient's body; and

an electrosurgical cutting element 3 disposed on a distal portion of the shaft proximal to the distal end 1a, which is actuatable between a radially retracted position (see figs. 2 & 6) and a radially extended position (see figs. 1, 5, 7 & 9-10) to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about

said tissue specimen (see column 3/lines 33-41 & 46-62; column 6/lines 24-32; column 7/lines 13-17).

In regards to claim 40, Okada et al. disclose an instrument assembly for isolating target tissue form an intracorporeal site, comprising:

a. an elongate shaft 1 which has a longitudinal axis and a distal end; and

b. an elongated electrosurgical tissue cutting element 3 which is longitudinally disposed on the elongate shaft 1 proximal of the distal end 1a of the shaft 1, which is radially extendable from a retracted position (see figs. 2 & 6) to a radially extended position (see figs. 1, 5, 7 & 9-10), which is capable of being rotated at least in part about the longitudinal axis in a radially extended arcuate position while receiving electrical power from a high frequency electrical power source to electrosurgically isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about at least part of the tissue specimen (see column 3/lines 33-41 & 46-62; column 6/lines 24-32; column 7/lines 13-17).

In regards to claim 41, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 further includes an electrical conductor 13 configured to electrically interconnect the electrosurgical tissue cutting element 3 to high frequency electrical power source (see fig. 3; column 4/lines 33-42).

In regards to claim 42, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 has a proximal end and a distal end and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended position (see figs. 1-2, 5-7 and 9-10).

In regards to claim 43, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 is configured so that the distal end is fixed and the proximal end moves toward the distal end in order to radially extend the electrosurgical cutting element 3 (see figs. 1-2, 5-7 and 9-10).

In regards to claim 44, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 comprises a monopolar electrode 3 (see figs. 1-2).

In regards to claim 46, Okada et al. disclose an instrument assembly wherein the instrument assembly further includes a sheath 14, which is axially movable between distal and proximal positions for selectively covering and uncovering the electrosurgical cutting element 3 (see fig. 4).

In regards to claim 47, Okada et al. disclose an instrument assembly including a proximal driver unit (9, 11) for controlling radial expansion and retraction of the electrosurgical cutting element 3 and rotation of the cutting element 3 about the longitudinal axis (see fig. 3; column 5/lines 50-65).

In regards to claim 49, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 is configured to be manipulated to segment the tissue specimen (see column 3/lines 46-62; column 4/lines 33-42).

In regards to claim 50, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 is capable of being manipulated to segment the tissue specimen after tissue specimen has been isolated from the surrounding tissue (see column 3/lines 46-62; column 4/lines 33-42).

In regards to claim 51, Okada et al. disclose an instrument assembly wherein the electrosurgical cutting element 3 is capable of being manipulated to segment the tissue specimen as the tissue specimen is being retracted from said radially extended position to said retracted position (see column 3/lines 46-62; column 4/lines 33-42).

In regards to claim 52, Okada et al. disclose an instrument assembly wherein the radially extended position comprises a first radially extended position, and wherein the electrosurgical cutting element 3 is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see figs. 1-2, 5-7 and 9-10).

In regards to claim 53, Okada et al. disclose an instrument assembly further comprising a cannula 14 having a lumen 21 for providing a passageway into the patient's body, the segments of the tissue specimen being removable from the patient's body through the cannula 14 (see fig. 4; column 5/lines 13-16).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. ('279) in view of Treat (US Patent No. 4,493,320).

Okada et al. disclose a system, as described above, that teaches all the limitations of the claim except Okada et al. do not teach a bipolar or monopolar electrode. However, Treat discloses a system comprising a bipolar electrode 24 (see fig. 3; column 3/lines 14-19; column 4/lines 44-49). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Okada et al. with a bipolar electrode similar to that of Treat in order to localize the cauterization to a small predefined volume of tissue and (see Treat, column 2/lines 31-41).

7. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. ('279) view of Burbank et al. (US Patent No. 5,980,469).

Okada et al. disclose a system, as described above, that teaches all the limitations of the claim except Okada et al. do not teach a driver unit for controlling both the shaft and sheath movements. However, Burbank et al. discloses a system comprising driver unit wherein the driver unit controls the movement of the sheath 268 and shaft 292 (see fig. 11A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Okada et al. with a driver unit similar to that of Burbank et al. since such a modification would amount to a design choice. It has previously been held that making integral (i.e. control of the movement of the sheath with that of the shaft) is not patentable--*See in re Larson, 340 F. 2d 965, 967, 144 USPQ 347, 349 (CCPA 1965); In re Wolfe, 251 F.2d 854, 855, 116 USPQ 443, 444 (CCPA 1958).*

8. Claims 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. ('279) in view of Malis et al. (US Patent No. 5,733,283).

Okada et al. disclose a system for isolating body tissue, comprising:

a. an elongate shaft 1 having a longitudinal axis and a distal end 1a; and

b. an electrosurgical tissue cutting element 3 disposed on the elongate shaft 1 which is radially extendable from a radially retracted position to a radially extended position, relative to the longitudinal axis, having an arcuate shape and being movable in said radially extended position and arcuate shape to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen; and

a source of high frequency energy connected to the tissue cutting element 3 (see figs. 1-2, 5-7 and 9-10; column 3/lines 33-41 & 46-62; column 6/lines 24-32; column 7/lines 13-17).

Okada et al. disclose a system, as described above, that teaches all the limitations of the claim except that Okada et al. do not teach a system comprising a distal end tissue cutting element. However, Malis et al. disclose a system comprising a bipolar distal end tissue cutting element 16 connected to a source of radiofrequency energy 12 (see fig. 1; column 3/lines 21-26, 44-51 & 59-62). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Okada et al. with a distal end tissue cutting element similar to that of Malis et al. in order to cut or coagulate tissue (see Malis et al., column 3/lines 44-51). Moreover, it would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to provide a system similar to that of Okada et al. with a bipolar or monopolar electrode similar to that of Malis et al. in order to ablate a defined or undefined volume of tissue as is well known in the art.

Double Patenting

9. The rejections are withdrawn due to Terminal Disclaimer.

Response to Arguments

10. Applicant's arguments filed July 5, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,050,992 to Nichols discloses an apparatus and method for treating tissue with multiple electrodes.

US Patent No. 5,318,564 to Eggers discloses a bipolar surgical snare and methods of use.

US Patent No. 5,376,094 to Kline discloses an improved actuating handle with pulley system.

US Patent No. 6,090,105 to Zepeda et al. discloses a multiple electrode ablation apparatus.

US Patent No. 5,417,697 to Wilk et al. discloses a polyp retrieval assembly with cauterization loop and suction.

US Patent No. 4,311,143 to Komiya discloses an apparatus for resecting tissue inside the body cavity.

US Patent No. 4,294,254 to Chamness discloses a surgical apparatus.

US Patent No. 5,437,665 to Munro discloses an electrosurgical loop electrode instrument.

US Patent No. 5,827,276 to LeVeen et al. discloses an apparatus for volumetric tissue ablation.

US Patent No. 5,542,916 to Hirsch et al. discloses a dual-channel RF power delivery system.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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